



PATENT APPLICATION
DOCKET NO. 01235-23625.CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Fikstad et al.	CERTIFICATE OF DEPOSIT UNDER 37 C.F.R. § 1.8
SERIAL NO.:	10/764,016	I hereby certify under 37 CFR § 1.8 that this correspondence is being facsimile transmitted to the USPTO or being deposited with the United States Postal Service with sufficient postage as first class postage in an envelope addressed to Commissioner of Patents PO Box 1450 Alexandria, VA 22313-1450 on the date indicated below.
FILED:	January 23, 2004	<u>Chandrashekhar Giliyar</u>
FOR:	PHARMACEUTICAL COMPOSITIONS WITH SYNCHRONIZED SOLUBILIZER RELEASE	Name
ART UNIT:	1614	<u>June 19, 2007</u>
EXAMINER:	Royds, Leslie A	Date of Deposit
DOCKET NO.:	01235-23625.CON	

DECLARATION OF CHANDRASHEKAR GILIYAR
UNDER 37 C.F.R. § 1.132

Mail Sto
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Chandrashekhar Giliyar declare as follows:

1. I hold a Bachelor's Degree in Pharmacy from the Govt. College of Pharmacy, Bangalore University, India, a Masters in Pharmaceutical Technology from University of Baroda, India, and a Ph.D. in Pharmaceutical Sciences, Mangalore University, India.
2. I have worked extensively in the Pharmaceutical field including working as a Manager of Product Development for GlaxoSmithkline Pharmaceuticals in Bangalore, India, and my current position as a Senior Scientist at Lipocine, Inc.

3. I am a named inventor on several issued United States patents and patent applications, including United States Patent Application Serial No. 10/764,016 (hereinafter '016), filed January 23, 2004, which I have recently reviewed.

4. I organized and directed the following experiments related to the dispersion of lipidic compositions. The experiments as presented in the declaration were conducted to demonstrate the variability of the characteristics or behavior (e.g. dispersion characteristics) of lipidic compositions containing varying amounts of the same components.

5. The experiment involved the preparation of five different example compositions using the same three lipidic surfactants, namely: 1) Polyoxy 35 Castor Oil, 2) Caprylocaproyl Macrogoglycerides, and 3) Linoleoyl Macrogoglycerides. The exact compositional makeup of each of the five example compositions is set forth in the following table:

Component	Surfactant Class	Composition (% w/w)				
		1	2	3	4	5
Polyoxy 35 Castor Oil (Cremophor ® EL)	Hydrophilic	28.0	20.0	17.0	15.0	3.0
Caprylocaproyl Macrogoglycerides (Labrasol ®)	Hydrophilic	67.0	50.0	40.5	35.0	7.0
Linoleoyl Macrogoglycerides (Labrafil ® M2125 CS)	Hydrophobic	5.0	30.0	42.5	50.0	90.0

6. The absorbance measurements of each of the five compositions were taken according to the following procedure: 1) 1 gram of the composition was placed in a clear glass container; 2) 99 grams of DI water was added to the container of Step-1; 3) the mixture formed in Step-2 was Vortexed (or shaken vigorously) for about 2 minutes, at 20° to 25°C; 4) the absorbance of the mixed solution of Step-3 was measured at 400 nm (1 cm path length)

7. The following absorbance measurements were made for each of the five samples:

Composition	1	2	3	4	5
Absorbance Value for the Dispersion @ 400 nm	0.01	0.32	1.35	3.14	>4.0

8. The above described experiment and accompanying experimental data demonstrate that compositions containing the same compound do not necessarily have the same functional characteristics. Although the above described experiment only exemplifies this principle for functional characteristic, such a principle can be accurately applied for other functional characteristics, including the functional characteristic set forth in the independent claims of the '016 application, namely the synchronization of the release of the drug and the solubilizer by a release modulator.

9. For the reasons stated above, I believe the invention set forth in the claims of the '016 application are novel and patentably distinct compositions known in the art.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statement may jeopardize the validity of any reexamination certificate issuing on the above-identified proceeding.

DATED this 18th day of June, 2007.


Dr. Chandrashekhar Giliyar